

## **General comment**

**Chapter 1 . 2 (General Information)** – Molluscan diagnostics

**Chapter 1 . 3 (General Information)** – Crustacean diagnostics

Recommendations: These are offered relative to three General Information chapters – 1.1, 1.2, and 1.3 – dealing, respectively with Fish, Molluscs, and Crustacea. In addition, rather than to comment on the detailed contents of each Chapter, the United States recommends that the FDC consider re-writing all these Chapters so that there is consistency in structure, format and content between them. Once completed, these Chapters can be re-submitted for comment. The United States recommends structuring each Chapter into sections as follows:

- Primary diseases and pathogens under consideration;
- General approaches of diagnostics and their importance to prevention, control and eradication, including clearly differentiating the significance of screening, preliminary (presumptive or tentative), and definitive (confirmatory) diagnostics and diagnostic tests, relating each to both subclinical (asymptomatic) and clinical disease;
- Significance, appropriate techniques, and use of clinical diagnostics (gross abnormalities on inspection, clinical signs and symptoms), histopathological diagnostics (light and electron microscopy), clinical pathology (serology, including immune responses and chemistry), bacteriology and virology diagnostics (culture and identification), and molecular diagnostics (monoclonal antibodies, PCR, DNA probes, etc).
- General conditions for validation of diagnostic tests, approval and accreditation of diagnostic laboratories by the competent authority, laboratory quality assurance and quality control (facilities, techniques and personnel);
- General approaches for sampling (noting specific requirements for individual diseases/pathogens when necessary);
- Appropriate techniques for surveillance, clearly differentiating active from passive;
- General requirements for reporting diagnostic results (on health certificates and, as necessary, to OIE);
- Utilization of diagnostic results in epidemiology.